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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,060	01/14/2002	Anand Baichwal	540.1004CON2	3558

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EXAMINER	
AZPURU, CARLOS A	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,060	BAICHWAL ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 26-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 26-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following rejections are cited in view of the Board of Appeal's suggestion during the remand of this application:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26, 28-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-19 of U.S. Patent No. 5,612,053 (US'053). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'053 sets out a particle for delivery via insufflation comprising a cohesive composite of a medicament and a pharmaceutically-acceptable carrier comprising a polysaccharide of natural origin (see claim 1). Xanthan

gum and locust bean gum are listed in claims 7 and 8, respectively. Particle size is set out as from about 0.1 to about 10 microns, and about 10 to about 125 microns (see claims 2 and 3). Medicament to gum ration is from about 0.5:100 to about 1:1 (see claim 10), and about 1:100 to about 1:2 (see claim 11). Cationic cross-linking agents comprise from about 01 to about 50% by weight and comprise an alkaline metal or alkaline earth metal sulfate, chloride, borate, bromide, citrate acetate or lactate (see claim 12). These may consist of potassium chloride and sodium chloride (see claim 13). Inert saccharide diluents are selected from monosaccharides, disaccharides and mixtures thereof (see claim 15), as well as dextrose, sucrose, galactose, lactose and mixtures thereof (see claim 16). Surfactants selected from anionic, cationic, amphoteric, non-ionic and mixtures thereof are added in claim 18. The particles are compressed to form a solid mass (see claim 19). Therefore, those of ordinary skill would have expected similar therapeutic results from the instantly claimed device which administers the same particle as set out in US'053 to the upper respiratory tract. The instantly claimed invention would have been obvious given the claims of US'053.

Claims 26-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,387,394 (US'394). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'394 sets out a particle for delivery via insufflation comprising a cohesive composite of a medicament and a pharmaceutically-acceptable carrier comprising a xanthan gum and locust bean gum (see claim 1). The ratio of xanthan gum to locust bean gum is set out in claim 2. Particle size is set out as from

about 0.1 to about 10 microns, and about 10 to about 125 microns (see claims 3 and 4). Medicament to gum ration is from about 0.5:100 to about 1:1 (see claim 5), and about 1:100 to about 1:2 (see claim 6). Cationic cross-linking agents comprise from about 01 to about 50% by weight and comprise an alkaline metal or alkaline earth metal sulfate, chloride, borate, bromide, citrate acetate or lactate (see claim 7). The amount of cross-linking agent is from about 1 to about 10% by weight (see claim 8). These may consist of potassium chloride and sodium chloride (see claim 9). Inert saccharide diluents are selected from monosaccharides, disaccharides and mixtures thereof (see claim 10), as well as dextrose, sucrose, galactose, lactose and mixtures thereof (see claim 12). Surfactants selected from anionic, cationic, amphoteric, non-ionic and mixtures thereof are added in claim 13. The particles are compressed to form a solid mass (see claim 14). Therefore, those of ordinary skill would have expected similar therapeutic results from the instantly claimed device which administers the same particle as set out in US'053 to the upper respiratory tract. The instantly claimed invention would have been obvious given the claims of US'394.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

ca